Patient Reported Outcomes with LASIK-2 (PROWL-2)

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Financial Disclosures

- I do not have any financial interests or relationships to disclose.

Study Objectives

- Evaluate the validity of a computer-based questionnaire assessing patient reported outcomes which is administered prior to and following LASIK surgery
- Evaluate the ease of survey administration as well as pilot the instrument prior to using it to measure outcomes in the general population
- Explore the prevalence of any functional limitations and their associated factors after LASIK surgery
- Explore the level of patient satisfaction, including the prevalence of any dissatisfaction and its associated factors at one and three months following LASIK surgery

PROWL-2

- Sites selected using criteria listed in NEI Request for Proposals (RFP)
  - » Infrastructure for clinical research (facilities and personnel)
  - » Certified on their laser platforms and perform at least 50 LASIK surgeries/month
  - » Experience recruiting and retaining subjects
- Conducted at 5 clinical sites across U.S.
  - » 20/20 Institute (Indiana)
  - » Durrie Vision (Kansas)
  - » Johns Hopkins University (Maryland)
  - » Stanford (California)
  - » Vance Thompson Vision (South Dakota)

Technology Utilized

- Excimer laser brands used in the study represented those with the largest market share*
  - » Wave-front guided
  - » Wave-front optimized
  - » Conventional

*Market share estimates provided by Market Scope, LLC based upon 2nd quarter 2014 survey data

Preliminary Results

Subject Participation

	PROWL-2
Total enrolled	312
Baseline Questionnaire	294
Surgery	292
Month 1 Questionnaire	265
Month 3 questionnaire	260

Demographics: Surgical Cohort

	PROWL-2
Gender	
Woman	53%
Ethnicity	
Not Hispanic or Latino	90%
Hispanic or Latino	4%
Unknown	6%
Race	
American Indian or Alaskan Native	1%
Asian	11%
Black or African American	2%
Native Hawaiian or Other Pacific Islander	2%
White	79%
Unable to specify	1%
Other	4%
Age	
Mean	31.5

Preoperative Clinical characteristics (Surgical Eyes)

		PROWL-2	
		Myopes n=568	**Hyperopes n=16**
Sphere	Mean	-3.6	2.5
Cylinder	Mean	0.7	0.9
Spherical Equivalent	Mean	-4.0	+2.0
	Range	-11.6 to -0.4	+0.1 to +4.1

3-Month Visual Acuity Outcomes

	PROWL-2 N=270
UDVA 20/20 or better	
OD	91%
OS	92%
OU	96%

>95% achieved 20/20 or better binocular UCVA at 3 Months

>90% achieved 20/20 or better monocular UCVA at 3 Months

3-Month Acuity / Refractive Safety Outcomes

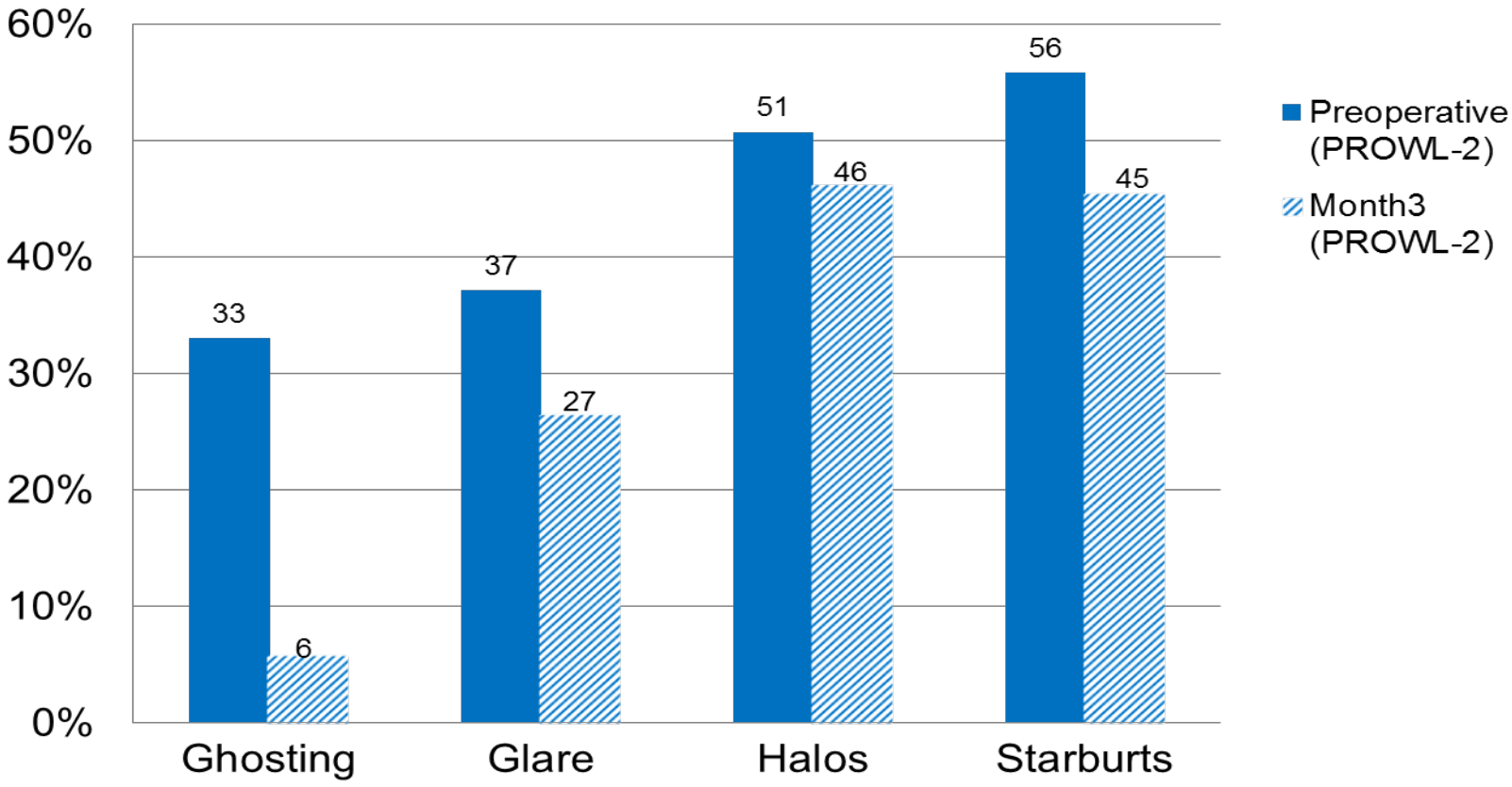
	PROWL-2 N=540 (eyes)
Loss of 2 lines or more BCVA	0 (0%)
BCVA worse than 20/40	0 (0%)
Increase of greater than 2D of cylinder compared to baseline	0 (0%)
BCVA worse than 20/25 if 20/20 or better pre-op	0 (0%)

Adverse Events (Eyes) by 3 Months

- Intraoperative
  - » 1 out of 584 (0.2%)
- Postoperative[1]
  - » 3[2] out of 584 (0.5%)

[1] Not including Loss of 2 lines or more of BCVA or Severe Symptoms
[2] 2 events not device related

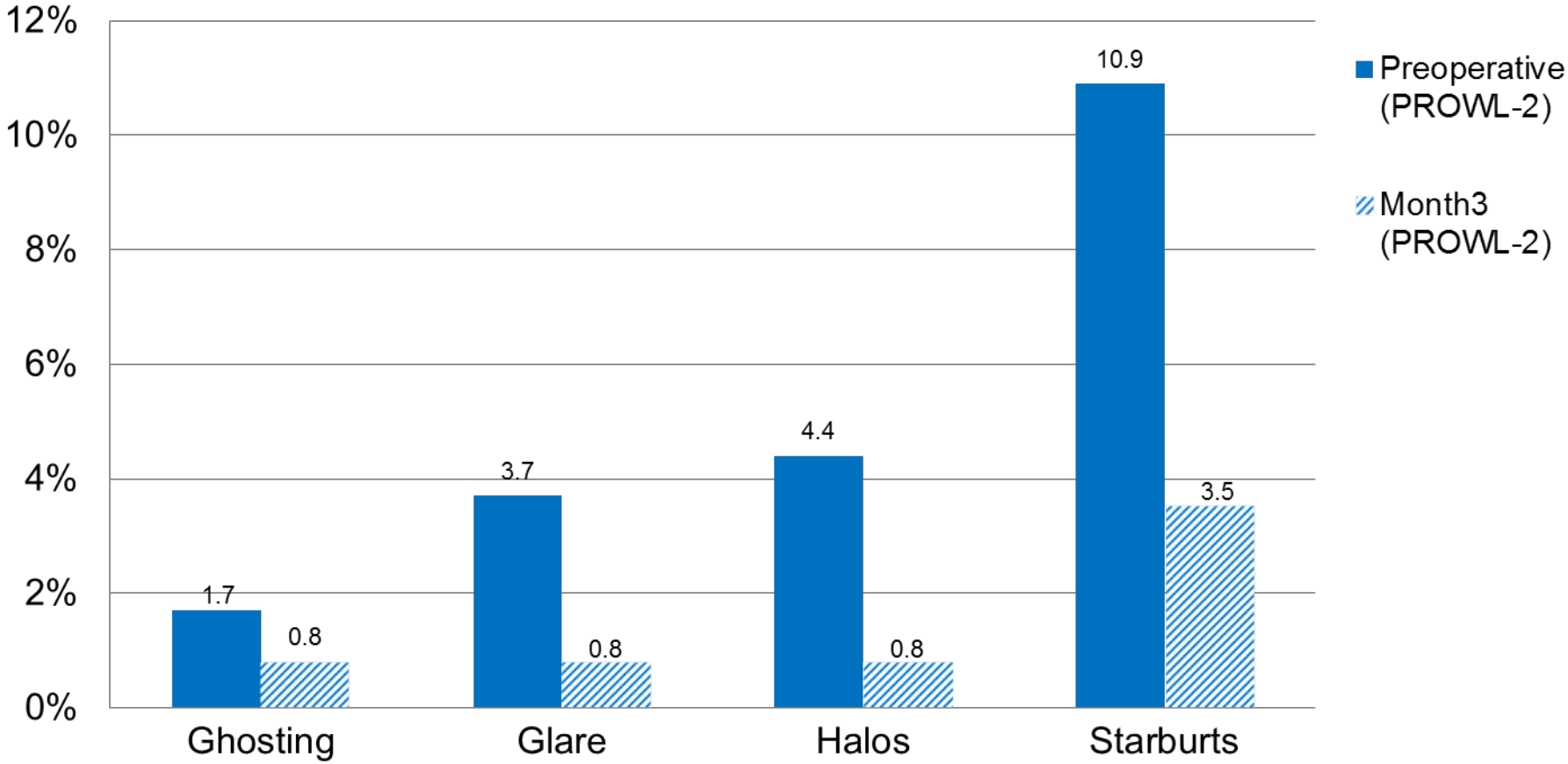
Prevalence of Symptoms: Pre-operative vs. Month 3



The prevalence of visual symptoms did not increase postoperatively

Prevalence of Bothersome (Very and Extremely) Visual Symptoms

(Preop w/ correction, 3 Months – w/o correction)

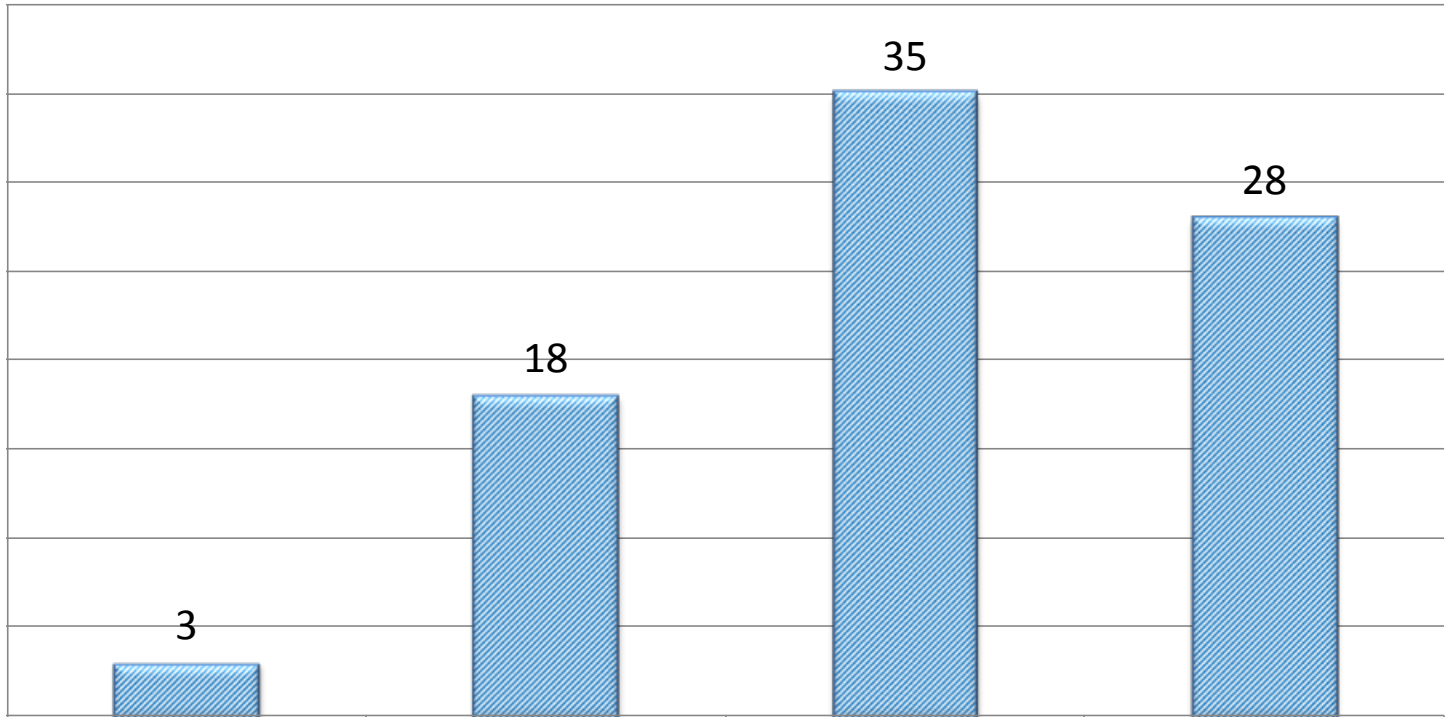


Visual symptoms were very or extremely bothersome in up to 4% of subjects without correction at 3 Months

Subjects Developing New Visual Symptoms

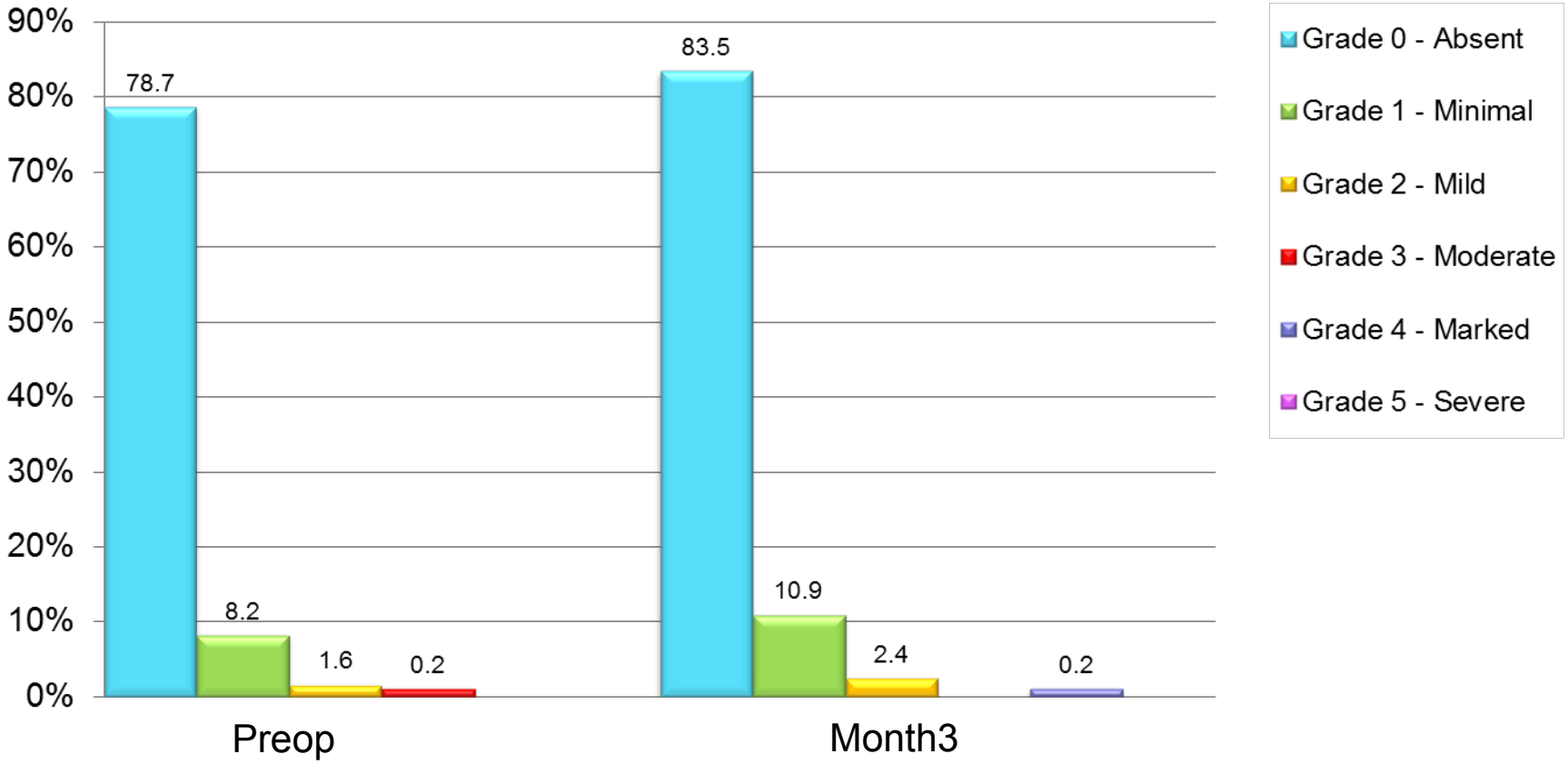
- 45% (31/69) of subjects with no visual symptoms pre-op developed new visual symptoms at Month 3

Subjects Developing New Visual Symptoms (did not have that symptom preop)



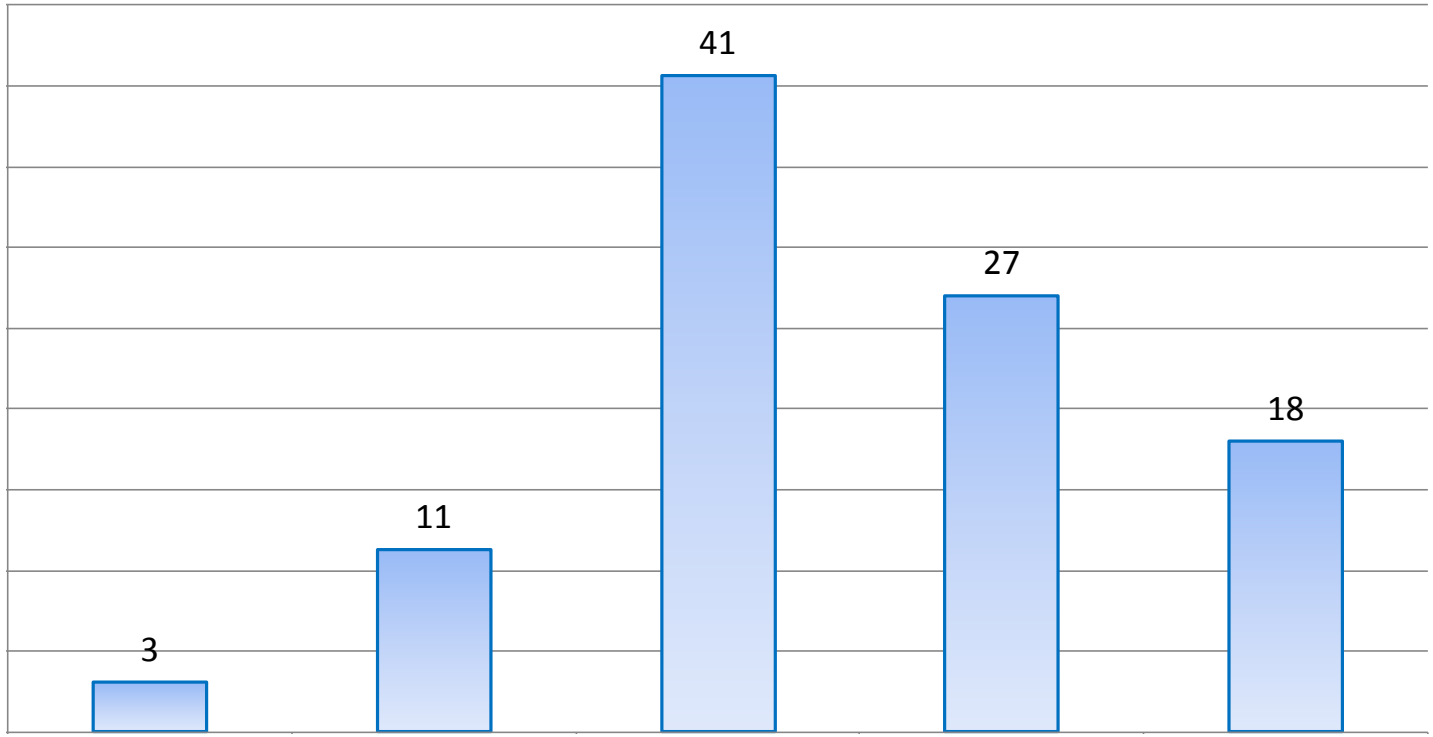
Up to 35% of subjects developed new halos

Distribution of Oxford Score staining (% of eyes)



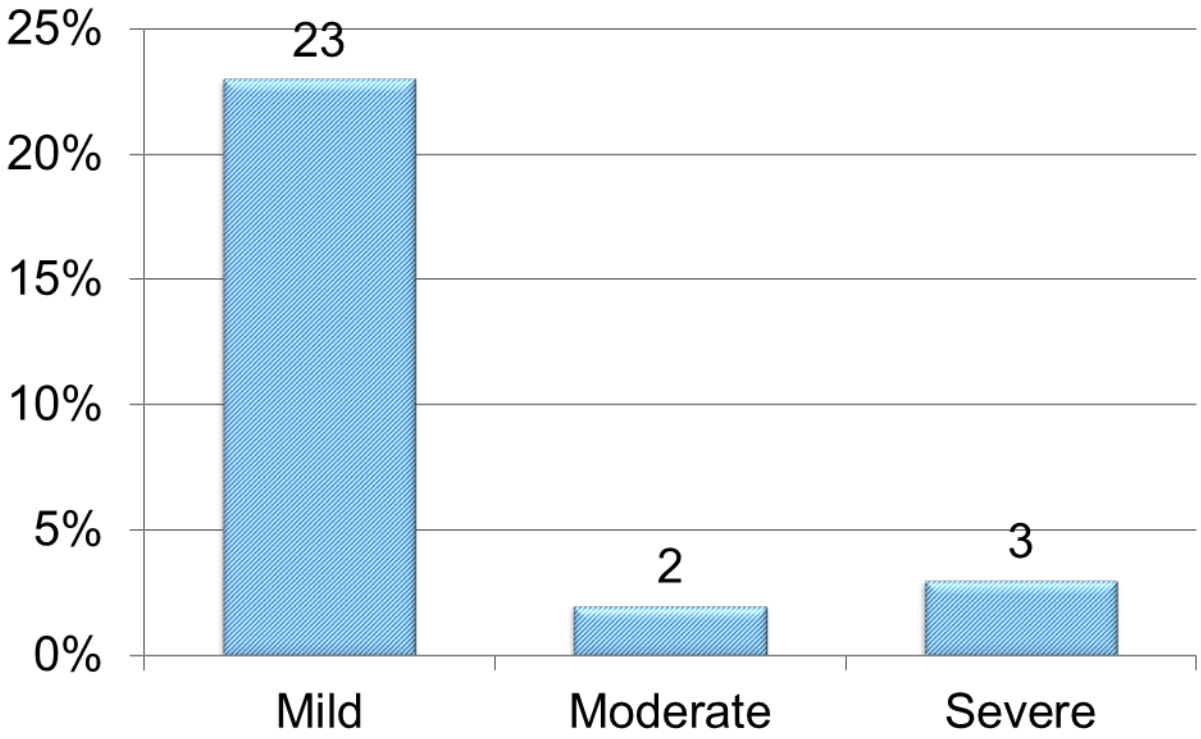
Up to 3% of eyes had staining of Oxford grade 2 or more at 3 Months

Dry Eye Symptoms (OSDI Categories) Change from Pre-op to 3 Months



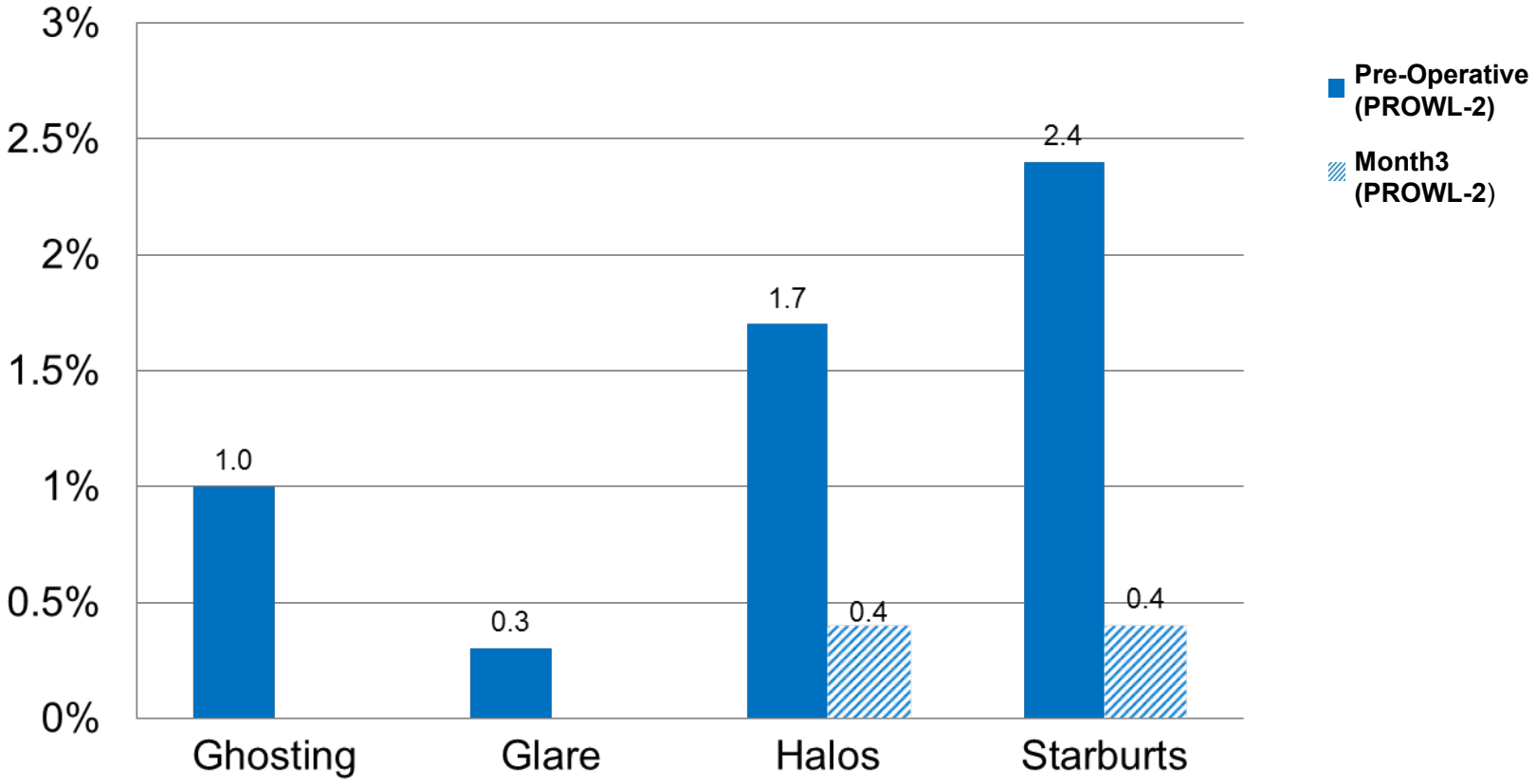
3% of subjects worsened by 2 or more levels of OSDI from Preop to 3 Months

Subjects Developing New Dry Eye Symptoms (OSDI Categories) at 3 Months



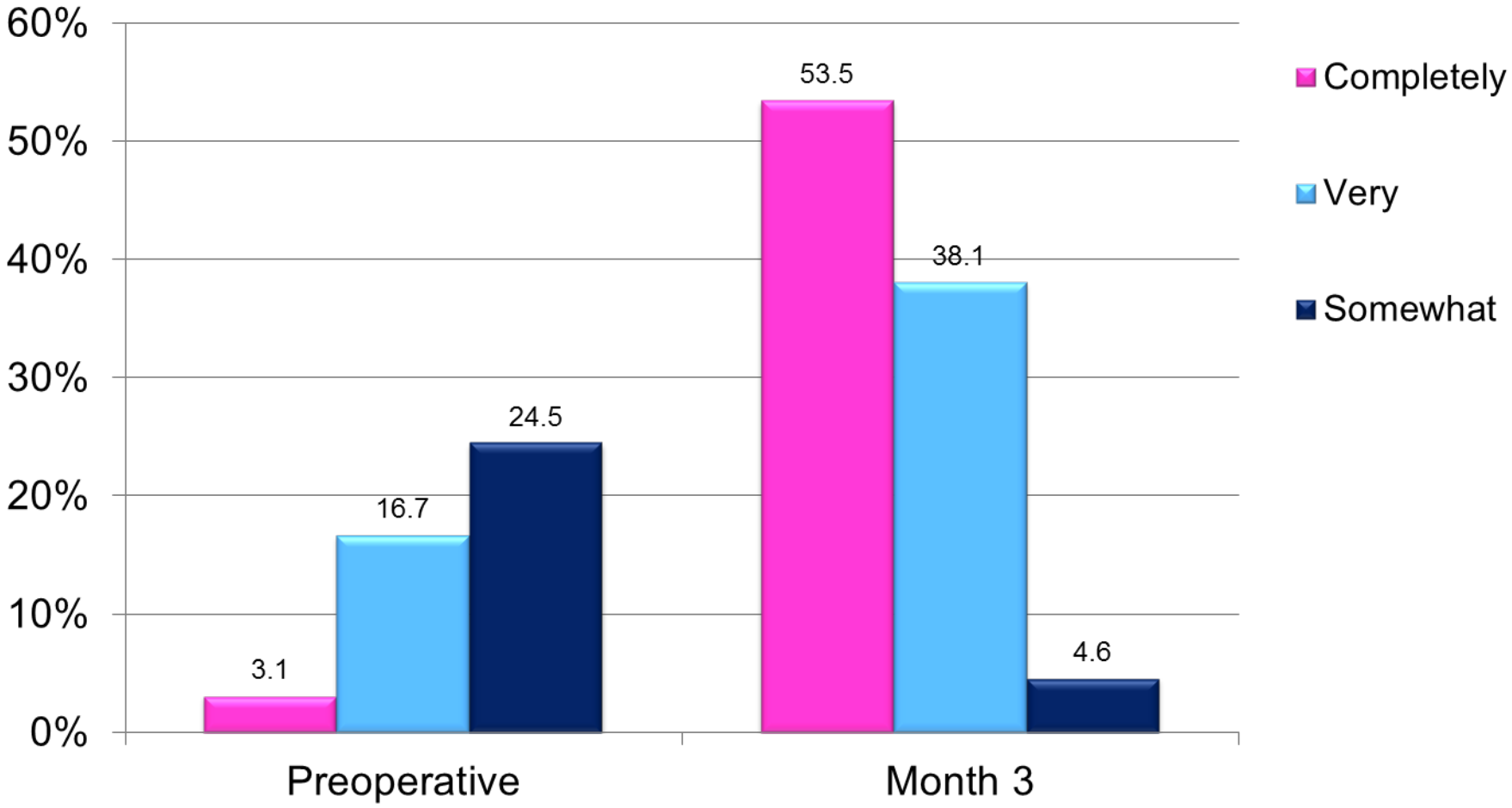
Up to 30% of subjects developed new dry eye symptoms

A Lot Of Difficulty With Or Inability to Perform Usual Activities Due To Visual Symptoms (Preop w/ correction, 3 Months – w/o correction)



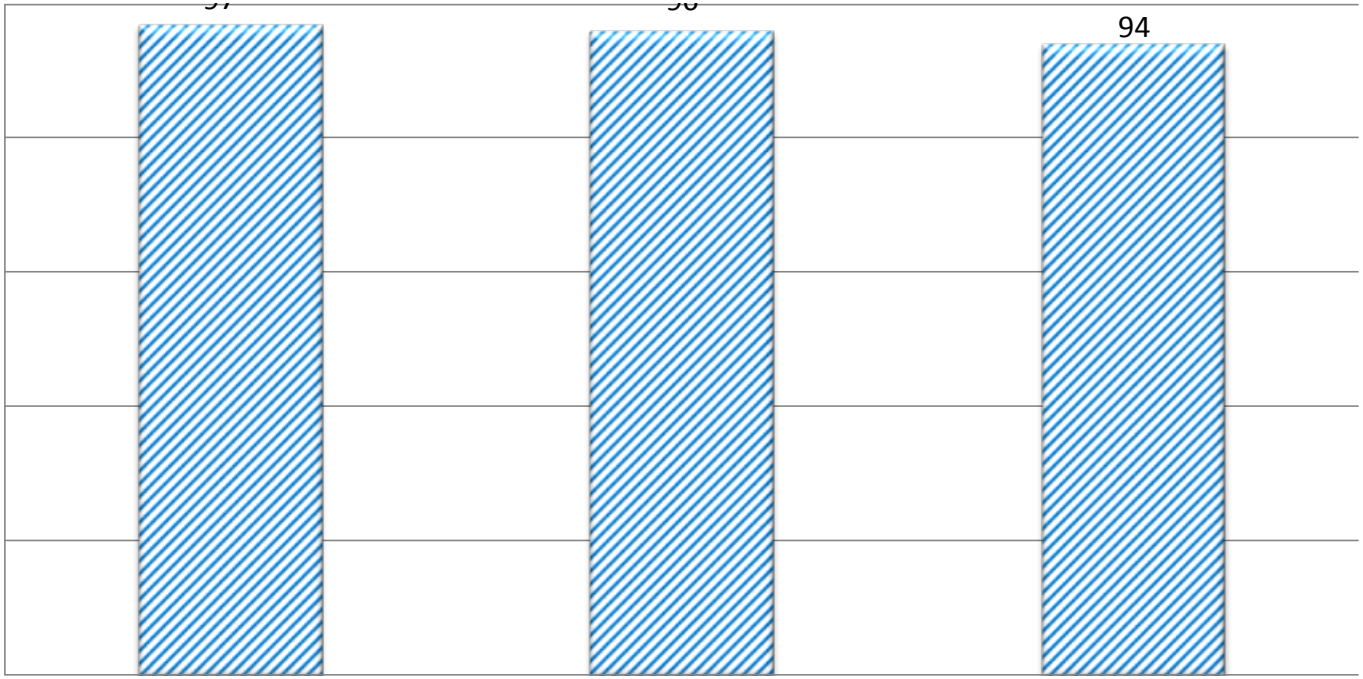
Up to 1% of subjects without correction experienced a lot of difficulty with or were unable to do usual activities due to visual symptoms at 3 Months

Overall Satisfaction with Present Vision



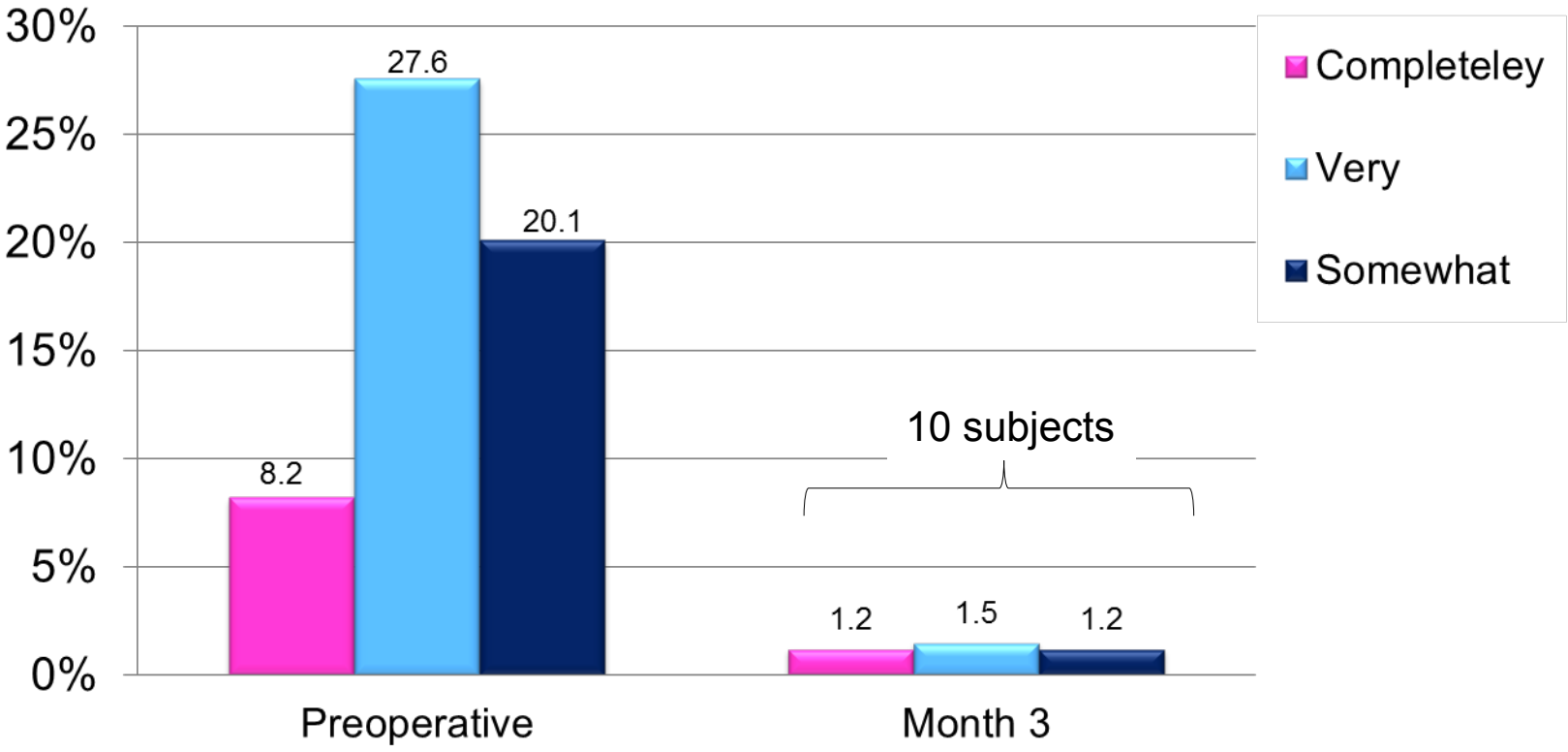
Greater than 96% of subjects were satisfied with their vision at Month 3

Additional Satisfaction Questions at Month 3



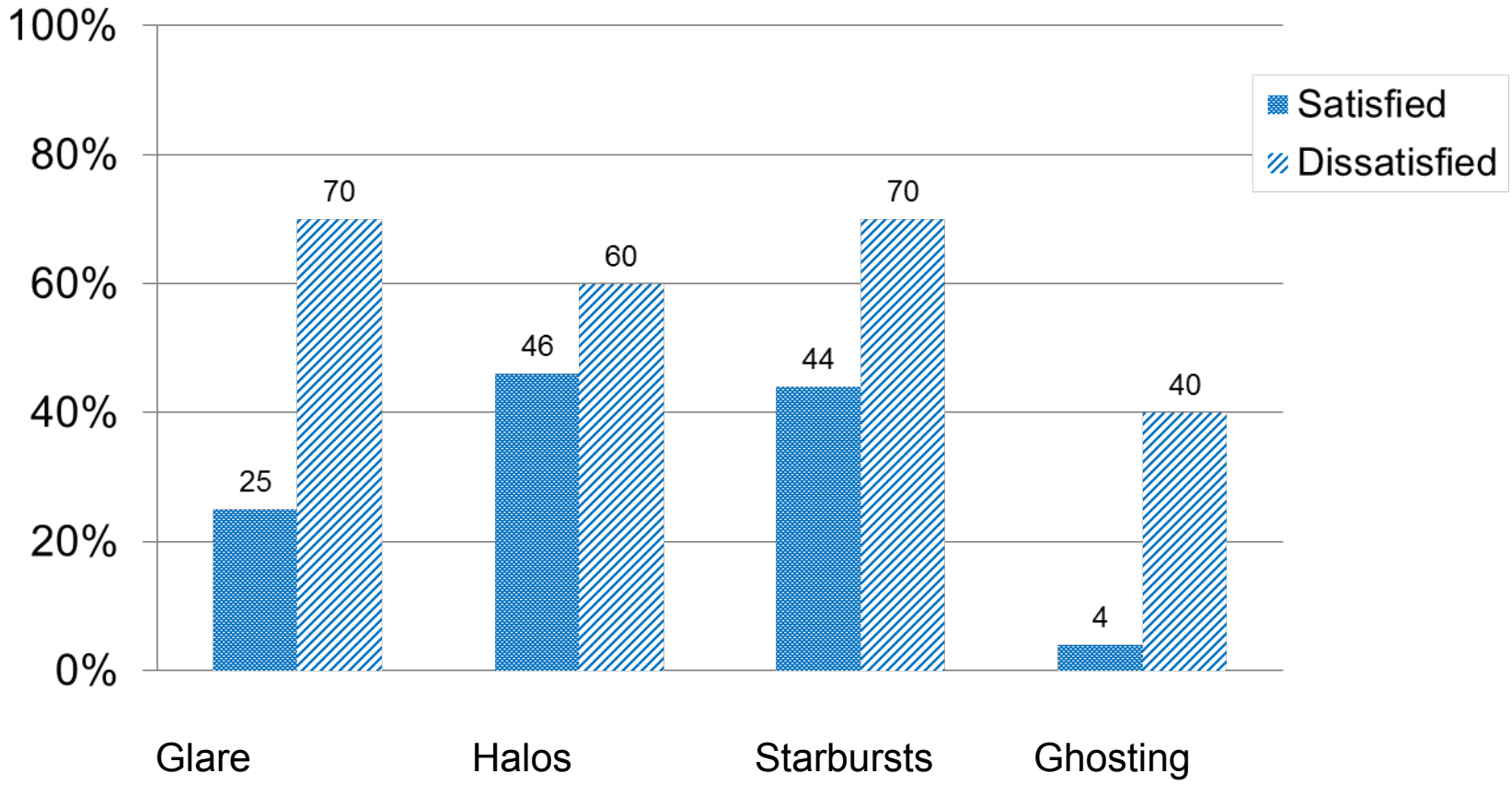
For the additional satisfaction questions, the satisfaction rate was 94% or greater

Overall Dissatisfaction with Present Vision



Up to 4% of subjects were dissatisfied with their vision at Month 3

Prevalence of Visual Symptoms at 3 Months Dissatisfied vs. Satisfied (Present Vision)



The majority of dissatisfied subjects reported visual symptoms

Summary (continued)

- Dry Eyes Symptoms at 3 Months
  - » Up to 30 % of subjects developed new dry eye symptoms
- Dissatisfaction at 3 Months
  - » Up to 4 % of subjects dissatisfied with vision
    - Potential association with presence of visual symptoms
    - Further analyses needed to explore additional associations

Summary (continued)

- Visual Symptoms at 3 Months
  - » Overall prevalence did not increase postoperatively
  - » Newly developed (at least one) in up to 45% of subjects who were symptom-free preoperatively
  - » Were “very” or “extremely” bothersome in up to 4% of subjects not wearing correction
  - » Caused a lot of difficulty with or resulted in inability to do usual activities in up to 1.0% of subjects not wearing correction